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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,286	10/16/2001	John Fruehauf	97,150-C	8043

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EXAMINER

HUMPHREY, DAVID HAROLD

ART UNIT PAPER NUMBER

1643

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/982,286	Applicant(s) FRUEHAUF, JOHN	
	Examiner David Humphrey	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. The finality of the rejection of the last Office action is withdrawn. See MPEP § 706.07(e).

Election/Restrictions

2. The restriction requirement in the Office Action mailed on 25 June 2005 is hereby vacated.

3. Claims 1-9 and 11-20 are pending.

Claims 1-9 and 11-20 are examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Double Patenting

5. The rejection of claims 1-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9 and 10 of U.S. Patent No. 6,303,324 (cited in Applicant's IDS), is withdrawn due to Applicant's terminal disclaimer, filed July 25, 2006 and approved August 1, 2006.

New Grounds of Objection

Claim Objections

6. Claim 1 is objected to because of the following informalities: line 21 should read, "sample is *greater* than the level of nuclear localization."

Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claims 1-9 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for making a prognosis of disease course in a human breast or prostate cancer patient comprising steps (a) through (d) of claim 1, does not reasonably provide enablement for a method for making a prognosis of disease course in a human breast or prostate cancer patient by preparing a prognostic index as recited in step (e) of claim 1. Furthermore, the specification while being enabling for a method of making a prognosis of disease course in a human breast or prostate cancer patient in claim 11 steps (a) through (e), does not reasonably provide enablement for a method of making a prognosis of disease course in any human cancer patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Art Unit: 1643

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue' not 'experimentation'." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention and the breadth of the claims: Claims 1-9 recite a method for making a prognosis of disease course in a human breast or prostate cancer patient comprising the steps (a) through (e) which includes preparing a prognostic index. Claims 11-20 broadly recite a method for making a prognosis of disease course in any human cancer patient comprising the steps (a) through (e) which includes preparing a prognostic index. The broadly recited claims are not commensurate in scope with the specification.

The state of the prior art and the level of predictability in the prior art: The prior art teaches that the claimed prognostic index would not be predictive for all cancer types. Hegde et al. (Arch Otolaryngol Neck Head Surg 124: 80-85, 1998)

Art Unit: 1643

teach that some tumors do not require angiogenesis and that gliomatosis grow as sheets of cells between membranes without the requirement of neovascularization, see page 84, bridging sentence from the left to the right column, and right column, lines 2-4. Additionally, Hegde et al. teach that they were unable to find any correlation between microvessel density and response to therapy or survival in head and neck cancer, see page 84, right column, third full paragraph, lines 1 and 2. Moreover, Hegde, et al. teach that those skilled in the art are in conflict as to whether a high level of vascularity is an indicator of aggressive tumor behavior in breast, bladder and prostate cancers or a better response to radiotherapy and chemotherapy, page 80, second full paragraph, lines 6-13. Similarly, Oshika et al. (Clinical Cancer Research 4: 1785-1788, 1998) teach they “found no significant relationship between TSP1 gene expression and clinical or pathological features of NSCLC (non-small cell lung cancer)” see page 1787, right column, 2nd paragraph, lines 1 and 2. Salveson et al. (International Journal of Cancer 84: 539-543, 1999) teach that “in vitro studies on melanoma cells showing the TSP-1 inhibited tumor cell proliferation” see page 542, right column, lines 3-5. Additionally, Salvesen et al. teach that “studies on non-small cell lung cancer, colon cancer and breast cancer do not show any significant association between TSP-1 expression and prognostic factors or prognosis,” see page 1542, right column, lines 16-20.

The amount of direction provided by the inventor and the existence of working examples: The specification provides support for using breast and prostate cancer cells with the measurement of three markers using the methods

Art Unit: 1643

recited in the examples, including the methods of measuring for the extent of microvascularization, the methods of weighing the results, making the index and determining the prognostic results. However, the specification has not provided adequate enablement for the full scope of the claims. It is not clear exactly how the prognosis is intended to be made using the claimed index in claim 1. In view of the prior art, claim 11 is not enabled for providing a prognosis for any human cancer.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed inventions without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC).

Quantity of experimentation needed to make or use the invention based on the content of the disclosure: In view of the Wands factors considered above, one of ordinary skill in the art would conclude that a method of making a prognosis by providing a prognostic index as recited in claim 1, step (e) and a method for making a prognosis of disease course in any human cancer as recited in claim 11, would require undue experimentation in order to use the invention as claimed by the Applicants.

Art Unit: 1643

Conclusion

7. No claim is allowed.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

August 22, 2006


LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER